Remarks

Claims 1-4, 8-11, 13-17, 21-23, 25, and 27-29 (all of the pending claims) are rejected under 35 USC 112, first paragraph, for failing to comply with the written description requirement. In particular, the Examiner says that Applicants have introduced new matter with the amendment to the claims that the crosslinking initiator "is not bound to a macromer or another polymer". The Examiner says that the specification does not disclose initiator not bound to a macromer or another polymer. This rejection is traversed.

Claims 1, 2, 8, 9, and 29 are rejected as being anticipated by U.S. Patent No. 6,007,833 to Chudzik et al. (the '833 patent). Claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 are rejected as obvious over the '833 patent in view of U.S. Patent No. 6,179,862 to Sawhney et al. (the '862 patent). These rejections are reiterated from the last Office Action and are again traversed.

The Written Description Rejection

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555,1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). (MPEP 2163).

In this case, the question is whether the specification as originally filed supports the amendment to the claims that the crosslinking initiator "is not bound to a macromer or another polymer".

The term "initiator" is used in the specification on page 9, lines 22 and 25 (referring to a photoinitiator); page 17, line13 (referring to a redox initiator); page 19, line 1 (referring to a borate initiator); and page 20, line 2 (again referring to a photoinitiator).

Use of the photoinitator Irgacure is discussed on page 9, lines 21-26 and in Example 13 and it is clear that the initiator is not bound to the macromer itself, or to another polymer. On page 9, a redox couple initiator is discussed- wherein one solution contains a reducing agent such as a ferrous salt and another solution contains an oxidizing agent such as hydrogen peroxide. Obviously neither initiator is bound to a macromer or other polymer. See also Examples 1-8 and 14-17. The use of borate as an initiator is discussed on page 19 and Examples 9-11. Again, it is

clear that the borate initiator is not bound to the macromer itself, or to another polymer. In fact, nowhere in the specification is a bound initiator discussed at all.

Accordingly, it is clear that Applicants have disclosed the use of a polymerizing initiator not bound to the macromer or another polymer and the amendments to the claims are not new matter or matter unsupported by the specification. This rejection should be reversed.

The rejection of claims 1, 2, 8, 9, and 29 over the '833 patent

The '833 patent teaches a crosslinkable macromer system. The system can be used as a wound dressing. The system includes two or more polymer/macromer-pendant polymerizable groups and one or more polymer/macromer-pendant initiator groups. The terms polymer and macromer are used interchangeably. Preferably, the polymerizable group and the initiator group are attached to (pendant from) the same macromer/ polymer- but they may be on different macromers/polymers. In either case, the initiator groups are attached to a macromer/ polymer.

The initiator is bound to either the macromer or to another polymer. It can be on the backbone of the polymer itself. The point of the invention is to avoid the use of free initiators that can present issues of toxicity, efficacy, and solubility (see col. 2, lines 15-20). To this end, the initiator is bound to the macromer/polymer.

In this most recent Office Action, the Examiner points to the teaching in the '833 patent at column 6, line 50 that a reductant can be incorporated into the polymer backbone as evidence that the initiator can be separate from the macromer backbone. This argument is illogical. In fact, the '833 patent teaches that the initiator can be separate from the backbone- as in pendant on the polymer but not incorporated into the backbone- but the whole point of the '833 patent is that the initiator is bound to the polymer in some manner- whether in the backbone itself, or pendant from the backbone.

The '833 patent does not teach or suggest that the composition is applied to a wound via spraying. The '833 does specify methods of delivery of the composition, contrary to the statement otherwise by the Examiner, and those methods are not inclusive of spray delivery. The Examiner cannot say that the reference teaches the specific means of spray delivery simply because it contains a generic teaching that the composition is applied to a wound.

Claim 1 recites a wound dressing that includes at least two aspects that are not taught by the '833 patent: 1) the use of an unbound initiator and 2) a wound dressing that is applied via spray.

The rejection of claims 3, 4, 10, 11, 13-17, 21-23, 25, 27, and 28 over the '833 patent in view of the '862 patent

The '862 patent teaches a method for forming a tissue adherent barrier in situ using a sprayer to deliver crosslinkable fluids. One of the fluids specifically described as suitable in the method is a solution of a polyethylene glycol (PEG) based macromer. The macromer includes a water soluble core oligomer, having biodegradable extensions that are capped with polymerizable end groups. It is true that PVA is listed as a possible water soluble core oligomer. However, the only macromer specifically discussed is a PEG- oligolactyl-diacrylate macromer which has a PEG core unit, a polyhydroxy acid extension on each end, and an acrylate end group on each end. PEG has only two hydroxyl groups - at each terminus- to which the crosslinkable acrylates can be fastened. The claimed macromers, on the other hand, because they are based on PVA, have crosslinkable groups on pendant chains- chains hanging from the backbone. A tremendous advantage of using PVA rather than PEG is that there are many available hydroxyl groups to which crosslinkable or other groups can be attached, and not just two, as in PEG. Thus, the use of PVA as the backbone of the macromers claimed in the present application offers advantages unexpected and unforeseen by the prior art.

The '862 and '833 patents are cited in combination as rendering the claims obvious. Applicants agree with the Examiner that the '833 patent does not teach delivery by spray, NO as an active agent, redox initiation, or that the dressing debrides the wound when removed (see the previous Office Action, paragraph spanning pages 4 and 5). As discussed above, the '833 patent also does not teach a composition having an initiator not bound to a macromer/polymer. As was discussed in previous correspondence between the Applicants and Examiner, the '862 patent does not teach or suggest the PVA based macromers that are used in the present invention.

There exists no reason to combine the teachings of the references. In fact, as discussed above, the '833 patent teaches away from the invention recited in the claims. Moreover, even if the references are combined, the claimed invention does not result. The combined patents do not

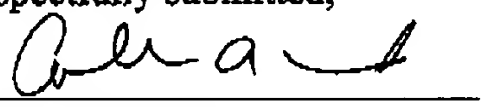
teach a wound dressing formed by spraying a PVA macromer having one or more pendant crosslinkable groups.

The law requires that there be- in the references themselves- some motivation to combine the references. Nowhere does the '833 patent suggest that it would be beneficial to spray the composition taught therein and form a wound dressing. Nowhere does the '862 patent teach that it would be beneficial to use a PVA macromer having one or more pendant acrylamide groups containing olefinically unsaturated groups.

Conclusion

Reconsideration of the claims is respectfully requested.

Respectfully submitted,



Collen A. Beard
Registration No. 38,824

Law Office of Collen A. Beard, LLC
P.O. Box 1064
Decatur, Georgia 30031-1064
(404).373.5065

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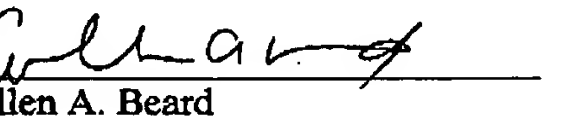

Collen A. Beard

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